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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,431	03/06/2002	Siba K. Samal	108172-00070	2502

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EXAMINER

HURT, SHARON L

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/926,431	Applicant(s) SAMAL ET AL.	
	Examiner Sharon Hurt	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 19, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 19 and 26-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

The amendments to claims 1 and 24 filed June 1, 2006 are acknowledged. Claims 8-18 and 20-25 have been withdrawn. Claims 1-7, 19 and 26-27 are pending and under examination.

### ***Response to Arguments***

#### ***Rejections Withdrawn***

The rejection of Claims 1-3, 5, 15 and 19 under 35 U.S.C. 102(b) as being anticipated by Stone has been **withdrawn** in view of applicant's arguments filed June 1, 2006, which were persuasive.

The rejection of Claims 26-27 under 35 U.S.C. 103(a) as being unpatentable over Millar et al. and Peeters et al. in view of Schijns et al. has been **withdrawn** in view of applicant's arguments, which were persuasive.

#### ***Rejections Maintained***

The rejection of Claims 1-7, 19 and 26-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **maintained**. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed June 1, 2006 have been fully considered but they are not persuasive. Applicant argues that "Newcastle disease virus Z" is sufficiently described by the

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specification and originally filed claims. However, since nowhere in applicant's specification is it set forth that the virus of claim 1 is designated a "Newcastle disease virus Z", it is unclear if the virus described in the specification is the same virus referred to in the claims. The term "Newcastle disease virus Z" is not found in the specification nor is it defined anywhere in the specification. Removal of the "Z" from the claims would be remedial.

The rejection of Claims 1-3, 5, 15 and 19 under 35 U.S.C. 102(a) as being anticipated by Millar et al. (Journal of Virology, 1988, Vol. 69, pages 613-620) is **maintained**. Applicant's arguments filed June 1, 2006 have been fully considered but they are not persuasive.

Applicant argues that "Millar et al. does not teach or suggest a "genetically engineered live attenuated Newcastle disease virus Z" of claim 1, much less a vaccine thereof". The claims have been amended by adding in the limitation of "genetically engineered live attenuated" Newcastle disease virus Z. However the term "genetically engineered live attenuated" is not defined in the specification. Furthermore, in the absence of the definition of "genetically engineered", the claimed invention is not readably distinguishable as different over the product in the reference of record. The definition of attenuated is "less virulent or weakened" (see Life Science Dictionary reference), which describes the lack of virulence of the Ulster strain (Millar et al., Abstract). Therefore the product in Millar et al. is not patentably distinct from the claimed invention absent some structural difference in the virus of the instant invention and the virus of Millar et al.

The instant claims are drawn to a product-by-process. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself

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without consideration of the process for making it (*In re Thorpe* 227 USPQ 964 (Fed. Cir. 1985)). In the present case, the final product does not appear to be distinguished by any particular features or characteristics over the product of the prior art as a result of the process by which it is made. Thus, the claimed product is not patentable over the product of the prior art absent any distinct difference in the products themselves (see MPEP § 2113).

The rejection of Claims 4 and 6-7 under 35 U.S.C. 103(a) as being unpatentable over Millar et al. and Peeters et al. is **maintained**. Applicant's arguments filed June 1, 2006 have been fully considered but they are not persuasive.

Applicant argues that Peeters et al. does not satisfy the deficiencies of Millar et al. Applicant further argues that Peeters et al. does not teach or suggest a specific attenuating mutation that will be used to attenuate Newcastle disease virus. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the present case, Millar et al. teaches the specific attenuating mutations of the claims, as was discussed *supra*. Peeters et al. teaches a process to generate new attenuated live vaccines with enhanced properties (Abstract). Peeters et al. also teaches about genetic modification wherein mutations, deletions, insertion or other modifications are methods to attenuate or modify the virulence of avian-paramyxovirus (Newcastle disease virus family) (page 18, lines 24-28).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

November 2, 2006

  
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